

## **Summary of the Meeting of the Environmental Laboratory Advisory Board (ELAB) December 5, 1995**

The Environmental Laboratory Advisory Board (ELAB) convened on December 5, 1995 at the Hyatt Regency Hotel in Arlington, Virginia, at 9:00 a.m. The meeting was led by Chair, Ramona Trovato of USEPA Office of Radiation and Indoor Air. A list of handouts is provided in Attachment A. A list of members present is given in Attachment B.

### **1. PROCEDURES FOR MEETING**

Ms. Mourrain described the regulations under which ELAB operates. As a committee chartered under the Federal Advisory Committee Act (FACA), ELAB provides a vehicle by which EPA can receive public comments and input. ELAB is required to give notice in the Federal Register 15 days prior to any meetings. ELAB is required to have balance among the representation of committee members - private industry, environmental groups, local government, etc. All meetings and minutes, are open to the public. Ms. Mourrain noted that specific approval from the Deputy Administrator had been given for this meeting of ELAB due to the continuing resolution on the budget.

It was noted that the charter calls for 2 meeting per year. A period of the meeting will be devoted to public comments and written comments are encouraged. It was also noted with appreciation that Board members have agreed to support their own expenses.

### **2. BACKGROUND**

#### **Problem Statement**

In early 1990 the private sector solicited EPA's assistance to resolve the problems associated with laboratory accreditation.

Several interrelated problems were cited:

1. Inconsistent laboratory inspections were occurring, resulting in a lack of reciprocity among the various states' programs. The status of a laboratory's accreditation in one state is frequently not communicated to other states, which have granted accreditation to that same laboratory.
2. As testing requirements expanded, accreditation was needed in areas where accreditation was not previously administered.
3. Potential clients of a laboratory, both private and governmental, did not have ready access to the labs accreditation status.
4. Labs trying to meet International Standards as well as EPA standards need a consistent accreditation program for business purposes.
5. Under the existing accreditation system, some labs are never subject to on-site assessments.

## **Role of the Environmental Monitoring Management Council (EMMC)**

One of the missions of the EMMC was to study the feasibility and advisability of a national environmental accreditation program. The EMMC *Ad Hoc* Panel on Laboratory Accreditation reported that a program was feasible and recommended that advice from the entire laboratory community be solicited.

The Committee on National Accreditation of Environmental Laboratories (CNAEL) was subsequently established with Milton Bush as the chair. It enjoyed the support and membership of states, private industry, regulated industry, academia, environmental organizations, and accrediting bodies.

As a result, four subcommittees were established:

1. Needs Subcommittee
2. Alternatives Subcommittee
3. Scope Subcommittee
4. Elements Subcommittee

After a year of detailed study it was determined by EMMC that an accreditation program operated by non-federal agencies with federal oversight should be established.

The State/EPA-Focus Group was convened to develop an implementation plan and draft a set of standards. It included ten states (CA, NJ, NY, TX, CO, MD, MN, MI, FL, SC) and all of the EPA program offices.

Several aspects of the accreditation program were identified:

1. Standards were to be established jointly by the states and EPA,
2. Standards issued by the EPA would be adopted by the states,
3. Any state in the program would adopt the accreditation of any other state in the program,
4. EPA would ensure uniformity of program implementation by evaluating the states' individual programs.

A draft proposal for a National Environmental Laboratory Accreditation Conference (NELAC) was published in the Federal Register. It was modeled after the National Conference on Weight and Measures (NCWM) of the National Institute of Standards and Technology (NIST). It was noted to the Board that the NELAC is a standard setting process only and will not be an implementation or approval process for the laboratories or the states.

Each committee is composed of 5 Voting Members and 5 Contributors, and meet most frequently by teleconference. The standards of each committee is posted on EPA's Technology Transfer Network (TTN) bulletin board which offers ready access to all users through telephone dial-up access or via the Internet. NELAC Interim Meetings offer the

opportunity for hands on committee work. Annual Meetings of NELAC are planned to conduct voting on the various standards. The resulting voluntary standards will be published on the TTN, at which point the states may adopt the procedures. With full reciprocity among all states, one state's accreditation will be accepted throughout the country

EMMC has expressed interest in continuing its support of NELAC, as it is expected that all EPA programs will benefit. The NELAC staff is projected to be at 3 full-time staff by FY96.

### **NELAC Measures of Success**

At the first NELAC Annual meeting, held in February, 1996, 47 States and Territories were represented. The initial NELAC Constitution and Bylaws were adopted by the voting members. A poll was taken at the end of meeting to determine group consensus, with 96% supporting NELAC, except among the GLP community in which there was only 12% in support.

### **NELAC Vision - Cooperation of States and EPA**

Based on the above foundation it is envisioned EPA would oversee state accreditation programs. Participating states and other responsible federal agencies would recognize the resulting accreditations granted by one another.

### **Summary**

It is expected that there will be regular modifications to NELAC standards and policies. The Interim meeting provides opportunity to talk with the standard-setting community; the Annual Meeting provides the voting opportunity. The *Ad Hoc* Panel believes that the NELAC standards should cover almost all EPA programs. It is acknowledged that laboratories want accreditation that will be accepted locally, statewide, and internationally. Hence, NELAC standards should cover all environmental programs under EPA's purview.

## **3. DISCUSSION**

Following the above presentation, the floor was opened for general discussion.

It was noted that a third party accreditor can collect findings but is not authorized to grant accreditation. The accreditation program in Michigan was cited as an example.

It was noted that there are already many state accreditors who will not accept the findings of other accreditors. The question was raised as to whether bringing in a third party accreditor might cause even more problems.

It was noted that GLPs are not delegated to the state - the Food and Drug Administration (FDA) and EPA are oversight agencies and conduct any needed audits for GLPs. It was noted that both EPA and FDA have limited resources. The possibility of using third party accreditors as the states have done was raised.

It was noted that charging small labs the same fee for accreditation as large labs could cause problems.

It was suggested that the states must be allowed flexibility in deciding on fees for accreditation.

It was noted that individuals who do not have a vote in NELAC (local government, private industry, Indian tribes) can participate fully in the ELAB activities. ELAB reports to NELAC Board of Directors, EMMC, and EPA's Deputy Administrator.

#### **4. ISSUES AND CONCERNS OF INDIVIDUAL BOARD MEMBERS**

Linda Christenson, of IAETL, noted that accreditation efforts have been in process since 1989 to diminish the costly and redundant impact of multiple accreditations. It appears feasible to develop a system which is administered by private/public partnership, with federal oversight. An important goal of the effort should be to provide data that is nationally recognized, while providing motivation for continuing private sector improvements as a result of NELAC activities. The possibility of private sector participation in NELAC voting, and pilot programs to test the implementation of an accreditation program were also mentioned as desirable.

Allen Verstuyft, representing the American Petroleum Institute (API), stated that it is the API perspective that NELAC should be a partnership, not a command type program. Its purpose should be to promote high quality and consistency in data. There is a need to minimize conflict and the high costs that result. The regulated industries and regulators need consistency and quality fitness reviews to gain the public trust. Under the present system the cost to the individual laboratories is great with marginal improvement in data quality. He views his role in ELAB as serving as a voice for the general membership.

Milton Bush, of the 'M Companies, stated that his vision for the private sector is to have a major role in ELAB and to use ELAB for practical advice to EPA. He envisions communications to be two-way, with the potential for eliminating administrative roadblocks.

Frieda White, representing the Navajo Tribal Utility Authority, noted that problems are appearing in deep wells, and the contamination is traceable to industrial activities. Flexibility in regulations should take into account small systems where industry is not a leading factor.

Thomas Coyner, representing A2LA, expressed interest in better understanding how a third party accreditor in the private sector can participate in NELAC. Currently, there is uncertainty in international accreditation experience, however it may be possible to find a way for third party accreditors to aid states. This would give options to states that presently are not active in accreditation due to limitations in funding, staffing, etc. He expressed the hope the NELAC Board will come to ELAB and present problems for a mutually beneficial solution.

Evelyn Torres, of the Fairfax County Water Authority, acknowledges the need for a lab accreditation program. She plans to represent the small utility labs perspective to ELAB.

Ann Marie Gebhart, of NSF International and representing non-profit third party accreditors, noted that she is relatively new to the NELAC process. Her focus is on drinking water and waste water analyses. She acknowledged the need to accredit labs, and that the accreditation be recognized in the US and internationally. Her company was the first to be involved in laboratory accreditation, and she recognizes the need for national accreditation standards.

John Henshaw, representing the Society for Quality Assurance (SQA), stated that he and SQA are committed to be part of the solution and not the opposition. He perceives key differences in the GLP program from NELAC's requirements and any outcome should enhance our efforts and not make them less effective. The environmental analysis sector has a need to keep costs down, reconciling the GLP requirements, agency to agency requirements, and international requirements. He noted that ISO 25 is not popular in the GLP laboratory community. He noted that a laboratory accreditation program may not eliminate industry on-site visits to laboratories. He also noted that there is more at stake than GLP labs, and that Germany has a GLP lab accreditation program run by the government.

Wilson Hershey, representing ACIL, stated that he is interested in achieving a system for both National and International accreditation. Currently, there is little incentive for state and national regulatory agencies to work together in this process. He stated that the decision making process should be shared by all stakeholders and that the private sector could have a role in accreditation.

Kathy Hillig, representing the Chemical Manufacturers Association (CMA), expressed her support of the development of a national lab accreditation program. Her concerns are for the need for reciprocity, the effect on small labs, and whether ELAB had time to deal with all GLP issues.

Cynthia Lee, representing Kenvirons, expressed interest in certification of field staff as well as certification of laboratory organizations. She noted that trying to keep up with all the states and federal regulations is a difficult role; small labs feel pressures by industry, but there are also state concerns to be addressed.

Roz Rolland, of the World Wildlife Fund and representing environmental groups and environmental issues, stated that these groups rely on (and must assume) the quality of monitoring data that they are receiving. She voiced support for any mechanism for uniform standards which will improve the job they are trying to do.

## **5. GENERAL QUESTIONS**

The topic of performance-based methods (PBM), with issues such as performance criteria (for precision, detection limits, etc.) specifications, was raised for discussion by the Board. General response was that PBM is a good idea, but options need consideration.

The response by the regulators will be pivotal, with state permit writers playing a key role. It is believed that the investment in a great deal of education will be required, without adequate change in requirements.

PBM may not be appropriate for all analyses; for example, solids have different properties than the liquid samples envisioned for PBM application. Matrix-dependent method performance (e.g., recoveries) will be a problem, requiring careful verification of a method's performance in the matrix of interest. However standardized procedures and recoveries are perceived to be too stringent.

The concern was voiced over the difficulty of identifying exactly what "method" was used to generate environmental data if a specific method is not prescribed. Additionally, responsibility for verifying the method's performance would be an essential activity.

The concern was voiced that NELAC standards should be a "good standard" not the "lowest common denominator".

Organizations who develop the standards development should also do training - however, this can be viewed as a conflict of interest.

Data audits add another dimension of possible difficulties. Auditors would have to look at data and not the procedures used to generate it. This potentially will present whole new concerns about data audits. Ultimately an auditor could "drill down" and eventually reach sensitive, confidential, or trade secret information which may represent a competitive advantage. An additional issue is to have confidential data transferred to the accrediting agency. Securely storing and keeping this data will be an issue.

The petroleum companies review core environmental programs - the clean air act, drinking water, RCRA, etc. However, the API accreditation program focuses on petroleum testing and must also deal with issues that EPA requires be tested that were not covered by these acts.

## **6. CURRENT STATUS OF THE NELAC STANDARDS**

Dr. Robert Stephens, chair of NELAC, presented an overview of the current version of the six sections of the NELAC standards. He noted that this draft is the result of the standing committee's workings over the last 10 months, and it has been substantially revised since the first NELAC Annual meeting. The main change clarifies voting status, including one representative from each cabinet level office.

## **7. FUTURE ACTIVITIES OF ELAB**

Several activities are planned in which ELAB may participate as a Board, as well as individuals. There will be administrative meetings of the Board to ensure adequate communication and outreach. The TTN computer bulletin board will be maintained, and other ways to involve the community are desirable. A project involving cost-value added study is planned as are NELAC fact sheets for general distribution.

Voting on NELAC standards is planned for next spring, and the goal is to prepare the standards to present to the states for their adoption. It was noted that EPA will commit to perform specific essential functions at a future time. In this context, it is important for everyone comes along at the same pace since this process will probably take 3 - 5 years to achieve.

The GLP lab issues can be addressed in due course. The GLP labs are new to accreditation considerations, however accreditation would benefit EPA programs that deal with GLP labs.

## **8. SUBCOMMITTEE DISCUSSION**

The possibility of ELAB establishing a GLP subcommittee was raised. The Board was in favor of this possibility. However there were no volunteers for a chair's role due to lack of available time. The size (5-10 members) and representation on the subcommittees was discussed. Clear mission and structure of any established subcommittee is also needed, and it should report to the Board.

The meeting was adjourned by Chair Ramona Trovato

**Handouts Distributed to Board Members and to Observers  
ELAB Meeting December 5, 1995**

1. Agenda
2. US EPA Advisory Committee ELAB Charter
3. Summary of Legal Requirements -Federal Advisory Committee Act
4. Memorandum dated 10/30/95
5. AIHA Letter to Ramona Trovato
6. Supplement to NELAC Directory - ELAB
7. State of Illinois EPA Division of Laboratories - Position Statement at the Interim  
NELAC Meeting on NELAC/NELAP and the USEPA's Role In and Support of  
NELAC
8. Illinois EPA FAX



**Participants List**  
**ELAB Meeting December 5, 1995**

<b>NAME</b>	<b>AFFILIATION</b>	<b>PHONE</b>
Milton Bush	The 'M Companies	T: (703)533-9539 F: (703)533-1612
Linda Christenson	IAETL	T: (703)739-2188 F: (703)739-2556
Thomas Coyner	A2LA Analytical Products Group, Inc.	T: (614)423-4200 F: (614)423-5588
Ann Marie Gebhart	NSF International	T: (313)769-5351 F: (313)769-0109
Mr. John Henshaw	Society for Quality Assurance Monsanto Co.	T: (314)694-8830 F: (314)694-5500
Wilson Hershey	ACIL Lancaster Laboratories	T: (717)656-2300 F: (717)656-0450
Kathy Hillig	Chemical Manufacturers Assoc. BASF	T: (313)246-6334 F: (313)246-5226
Cynthia Lee	Kenvirons, Inc	T: (501)962-6400 F: (501)695-6411
Jeanne Mourrain, Designated Federal Official	USEPA/NERL	T: (919)541-1120 F: (919)541-4101
Roz Rolland	World Wildlife Fund	T: (202)778-9567 F: (202)293-9211
Evelyn Torres	Fairfax County Water Authority	T: (703)430-1170 F: (703)421-1834
Ramona Trovato, Chair	USEPA/ORIA	T: (202)233-9320 F: (202)233-9651
Allen Verstuyft	American Petroleum Institute Chevron Oil Company	T: (510)242-3403 F: (510)242-5320
Frieda White	Navajo Tribal Utility Authority	T: (620)729-5721 F: (520)729-2135